AccuReview

An Independent Review Organization
569 TM West Parkway
West, TX 76691
Phone (254) 640-1738
Fax (888) 492-8305

[Date notice sent to all parties]: September 20, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Surmontil 50mg #320

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This physician is Board Certified in Physical Medicine and Rehabilitation with over 16 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant is a male whom is being treated for back pain which is associated with a work related injury. He indicated that the pain started in the lower back and it's axial R>L, it does not shoot down his legs. The associated symptoms include tightness, stiffness and limited mobility. The pain is made worse with activity, twisting movements, and bending forward and turning from side to side. Pain is rated 3-4/10. He ambulates with the assistance of a cane.

05-11-15: Office Visit. CC: back pain. ROS: MS: complained of back pain, joint pain and stiffness. Impression: lumbago 724.2, Postlaminectomy syndrome lumbar region 722.83, lumbar radiculopathy 724.4, degen lumbar/lumbosacral intervertebral disc 722.52. Plan: continue current regimen and f/u in one month. Medicaitons: Oxycodone HCL 15, Lisinopril/HCTZ 20-12.5mg, Metformin HCL 500mg, Restoril 30mg, Surmontil 50mg.

06-08-15: Office Visit. CC: back pain. Pain rated 4/10. ROS: MS: complains of back pain. Impression: lumbago 724.2. Plan: TENS unit to address the tenderness in the lumbar, no changes to medications, RTC in 1 month.

06-23-15: UR. Reason for denial: The request for Surmontil, a tricyclic antidepressant, is not medically appropriate, or indicated here. While ODG's Chronic Pain Chapter Antidepressants for Chronic Pain topic does acknowledge that tricyclic antidepressants such as Surmontil are considered first line agent for neuropathic pain, as was/is present here in the form of the claimant's ongoing lumbar radicular pain complaints, this recommendation is, however, qualified by commentary made in ODG's Chronic Pain Chapter Medications for Chronic Pain topic, which notes that the analgesic effects to be a minimum of several months. The claimant does not appear to have responded favorably to the same.

The claimant was described as "Disabled " as of June 8, 2015 progress note in question. The claimant was having difficulty performing ADL as basic as ambulating, it was reported, on that date, and was using a cane to move about. Ongoing usage of Surmontil failed to curtail the claimants; dependence on opioid agents such as oxycodone, topical compounds, and/or anxiolytic agents such as Restoril. All of the foregoing, taken together, suggests a lack of functional improvement as defined by the measures established in ODG's Chronic Pain Chapter Functional Improvement Measures topic. Therefore, the request in not medically necessary.

07-29-15: UR. Reason for denial: The records reflect this is injury with axial back pain. The claimant's sleep is disrupted and he has minimal analgesic relief with no indication of functional improvement. The medical treatment guidelines note that tricyclic medications can be utilized for neuropathic pain but continuation should be based on its efficacy such as pain outcomes, function, and sleep quality. In that there is no indication of improvement, continued use is not supported per the medical treatment guidelines. Therefore, Surmontil 50mg #320 is not medically necessary. However, due to the nature of the medication, weaning is recommended.

09-01-15: Letter of Reconsideration. The claimant has been depressed, suicidal with severe insomnia after a devastating accident and after having surgeries and amputations. We found a medication that has helped him now for about 5 years, Surmontil. Prior to this medication he had numerous failures. Please reconsider approving Surmontil. Last year he tried a different antidepressant in the same family and regressed immediately.

09-06-15: Request for review. The claimant is taking this medication for depression, not pain management as stated in the denial letter. The claimant's DOI was. He sustained multiple injuries and early in his recovery period developed depression. He has been on antidepressants for a long time and undergone medication adjustments. Under Dr. care, the claimant has finally being on a medication that works for him and has improved his life without side effects. We are requesting to continue covering this medication.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

With additional clinical information provided after the two previous Utilization Reviews, the denial of Surmontil is OVERTURNED/DISAGREED WITH. This medication is prescribed for depression associated with chronic pain syndrome in this 22 year case requiring multiple surgeries and resulting in obvious dysfunction, disability and long term habituating medications. There is documentation of failure of other antidepressants, and a stable, effective, five year use of this medication without adverse side effects. There is also documentation of close monitoring of this and others medications of a complicated regimen. Therefore, after reviewing the medical records and documentation provided, the request for Surmontil 50mg #320 is certified and approved.

Per ODG:

Antidepressants for chronic pain	Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. (Saarto-*Cochrane*, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. (Additional side effects are listed below for each specific drug.) It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. (Perrot, 2006) (Schnitzer, 2004) (Lin-*JAMA*, 2003) (Salerno, 2002) (Moulin, 2001) (Fishbain, 2000) (Taylor, 2004) (Gijsman, 2004) (Jick-*JAMA*, 2004) (Barbui, 2004) (Asnis, 2004) (Stein, 2003) (Pollack, 2003) (Ticknor, 2004) (Staiger, 2003) Long-term effectiveness of anti-depressants has not been

established. (Wong, 2007) The effect of this class of medication in combination with other classes of drugs has not been well researched. (Finnerup, 2005) The "number needed to treat" (NNT) methodology has been used to calculate efficacy of the different classes of antidepressants. (Sindrup, 2005) See also the Stress/Mental Chapter: Antidepressants for the treatment of depression. Also see Comorbid psychiatric disorders.

Specifically studied underlying pain etiologies: (also see below for specific drugs)

Neuropathic pain: Recommended both tricyclic antidepressants and SNRIs (i.e. duloxetine and venlafaxine) as first line options. (Dworkin, 2007) (Finnerup, 2007) Other recent reviews recommended tricyclic antidepressants as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. (Saarto-Cochrane, 2007) (ICSI, 2007) All first-line treatment options for neuropathic pain had an NNT of 9 or less, with the lowest NNT reported for tricyclic antidepressants, which was 4. Serotonin-noradrenaline reuptake inhibitors had an NNT of 7, but this drug class was also associated with the highest discontinuation rate of first-line drugs with a NNH of 11. Pregabalin, gabapentin, and gabapentin extended release had NNTs of 8, 7, and 9 respectively, though gabapentins had the lowest NNHs of all drugs reported (25-32). Second-line drugs tramadol and capsaicin 8% patches had moderate to low effect sizes, but only low quality evidence was available for lidocaine patches and the NNT could not be calculated. (Finnerup, 2015)

Non-neuropathic pain: Recommended as an option in depressed patients, but effectiveness is limited. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. In guidelines for painful rheumatic conditions recommended by Perrot, it was suggested that antidepressants may be prescribed as analgesics in non-depressed patients, with the first-line choice being tricyclics initiated at a low dose, increasing to a maximally tolerated dose. (Perrot, 2006)

Specific studied disease states

Fibromyalgia: There have been 25 controlled trials that have studied the use of antidepressants for fibromyalgia, including 3 meta-analyses. Good results were found with duloxetine in fibromyalgia. (Arnold, 2007) Severa studies evaluated tricyclics. (Perrot, 2006) (Moulin, 2001) A review of two double blind, placebo controlled trials concluded that duloxetine was safe and effective in women with fibromyalgia for up to 12 weeks (with long-term studies needed). (Arnold, 2007) (Saarto-Cochrane, 2007) Duloxetine is approved by the FDA for treatment of fibromyalgia. (FDA 2010) Another review indicated that there is strong evidence that amitriptyline is effective for fibromyalgia and suggested that more information is needed regarding the role of SNRIs and SSRIs. (Goldenberg, 2007) Compared with placebo, the SNRIs duloxetine (Cymbalta) and milnacipran (Savella) are slightly more likely to reduce pain in patients with fibromyalgia, according to a new Cochrane meta-analysis, but they are not superior in terms of reducing fatigue and sleep problems or in improving quality of life, and they appear to cause more adverse effects. (Häuser, 2013)

Low Back Pain: Chronic: A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. SSRIs have not been shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition. (Chou, 2007) Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. SSRIs do not appear to be beneficial. (Perrot, 2006) *Acute:* Not routinely recommended. (Chou, 2007)

Radiculopathy: Antidepressants are an option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. (Dworkin, 2007)

Osteoarthritis: No studies have specifically studied the use of antidepressants to treat pain from osteoarthritis. (Perrot, 2006) In depressed patients with osteoarthritis, improving depression

symptoms was found to decrease pain and improve functional status. (Lin-JAMA, 2003)
Antidepressant discontinuation*:* Nearly all classes of antidepressants have been linked to discontinuation reactions that are distinct from recurrence or relapse of underlying psychiatric pathology. It does appear that discontinuation reactions can occur regardless of the particular indication for use. The most common research involves discontinuation of serotonin-reuptake inhibitors (Sertonin-discontinuation syndrome).
Symptoms: Symptoms of discontinuation vary between classes of antidepressants, and between different drugs in the classes. These may include changes in mental/psychological status (confusion, restlessness, agitation, anxiety, worsening of mood, panic attacks, dysphoria, manic symptoms, and decreased level of consciousness), neurological changes (tremor, rigidity, clonus, myoclonus, hyperreflexia, ataxia, and rigidity), autonomic changes (diaphoresis, shivering, mydriasis, nausea and diarrhea), and changes in vital signs (tachycardia, hypertension, hyperthermia, and tachypnea). Commonly patients describe both psychological and somatic symptoms (the latter described as flu-like, with or without gastrointestinal physical symptoms). Symptoms are thought to occur in at least 20% to 25% of patients upon discontinuing of serotonin-reuptake inhibitors (with reports of at least 50% with drugs with shorter-half lives such as paroxetine or venlafaxine). Symptoms tend to emerge within 2 to 5 days with a usual duration of 1 to 2 weeks. The primary risk factors for this reaction include use of antidepressants with shorter half-lives, longer duration of treatment, and abrupt discontinuation.
Differentiation from depression relapse or recurrence: Differentiating factors include looking for symptoms that are more likely to occur with discontinuation reaction (dizziness, electric shock-like sensations, "rushing" sensations, headache and nausea) as well as observing for rapid reversal of symptoms (complete resolution within 1 to 2 weeks of the taper/discontinuation is less likely to be due to depression). Later onset of symptoms (after at least two to three weeks of discontinuation/tapering) or prolonged symptoms (3 weeks or greater) are more commonly associated with a relapse of psychiatric pathology or another intercurrent disease. See also Weaning of medications (antidepressants) in the Mental Chapter for more information and references.
SPECIFIC ANTIDEPRESSANTS:
Tricyclic antidepressants are recommended over selective serotonin reuptake inhibitors (SSRIs), unless adverse reactions are a problem. Caution is required because tricyclics have a low threshold for toxicity, and tricyclic antidepressant overdose is a significant cause of fatal drug poisoning due to their cardiovascular and neurological effects. Tricyclic antidepressants have been shown in both a meta-analysis (McQuay, 1996) and a systematic review (Collins, 2000) to be effective, and are considered a first-line treatment for neuropathic pain. (Namaka, 2004) (Dworkin, 2003) (Gilron, 2006) (Wolfe, 2004) (Dworkin, 2007) (Saarto-Cochrane, 2007) This class of medications works in both patients with normal mood and patients with depressed mood when used in treatment for neuropathic pain. (Sindrup, 2005) Indications in controlled trials have shown effectiveness in treating central post-stroke pain, post-herpetic neuralgia (Argoff, 2004), painful diabetic and non-diabetic polyneuropathy, and post-mastectomy pain. Negative results were found for spinal cord pain and phantom-limb pain, but this may have been due to study design. (Finnerup, 2005) Tricyclics have not demonstrated significance in randomized-control trials in treating HIV neuropathy, spinal cord injury, cisplatinum neuropathy, neuropathic cancer pain, phantom limb pain or chronic lumbar root pain. (Dworkin, 2007) One review reported the NNT for at least moderate neuropathic pain relief with tricyclics is 3.6 (3-4.5), with the NNT for amitriptyline being 3.1 (2.5-4.2). The NNT for venlafaxine, calculated using 3 studies, was reported to be 3.1 (2.2-5.1). (Saarto-*Cochrane,* 2007) Another review reported that the NNT for 50% improvement in neuropathic pain was 2 to 3 for tricyclic antidepressants, 4 for venlafaxine, and 7 for SSRIs (Perrot, 2008).
Side-effect profile: Tricyclics are contraindicated in patients with cardiac conduction disturbances and/or decompensation (they can produce heart block and arrhythmias) as well as for those patients with epilepsy. For patients > 40 years old, a screening ECG is recommended

	prior to initiation of therapy. (Dworkin, 2007) (ICSI, 2007) They can create anticholinergic side effects of dry mouth, sweating, dizziness, orthostatic hypotension, fatigue, constipation, and urinary retention. (Finnerup, 2005) To minimize side effects, it is suggested that titration should be slow and based on the patient's response. (Namaka, 2004) An alternative choice may be a SNRI. (Finnerup, 2005) (Sindrup, 2005) (Dworkin, 2007) The muscle relaxant cyclobenzaprine is closely related to the tricyclic antidepressants so caution is advised when using cyclobenzaprine. (FDA, 2011) *Dosing Information:* *Amitriptyline*: *Neuropathic pain*: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007). *Fibromyalgia*: One review recommended the following dosing regimen: Start with low doses, such as 5-10 mg 1-3 hours before bedtime. Dose may be increased by 5 mg at two-week intervals; final dose is dependent upon efficacy and patient tolerability to side effects. Doses that have been studied range from 25 to 50 mg at bedtime. (Goldenberg, 2007) ***Selective serotonin and norepinephrine reuptake inhibitors (SNRIs):*** *Duloxetine (Cymbalta®)*: FDA-approved for anxiety, depression, diabetic neuropathy, fibromyalgia and chronic musculoskeletal pain. (FDA, 2010) Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. *Side effects:* CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs.2% for placebo), insomnia (8-13% vs. 6-7% for placebo). GI: nausea and vomiting (5-30%), weight loss (2%). Duloxetine can worsen diabetic control in some patients. It also causes sexual dysfunction. (Maizels, 2005) *Dosing:* 60 mg once a day as an off-label option for chronic pain syndromes. Dosage adjustment may be required in patients with renal insufficiency. *Venlafaxine (Effexor®):* FDA-approved for anxiety, depression, panic disorder and social phobias. Off-label use for fibromyalgia, neuropathic pain, and diabetic neuropathy. *Side-effect profile:* CNS: (≥ 5%) drowsiness, weakness, dizziness, dry mouth, insomnia, nervousness/anxiety (13/6% vs. 6/3%), tremor, headache, seizures. GI: N&V, constipation, weight loss (2-18%). Pre-existing hypertension should be controlled. Cholesterol may be increased (5%). Sexual dysfunction has also been noted. (Maizels, 2005) (ICSI, 2007) *Dosing: Neuropathic pain (off-label indication):* 37.5 mg once daily, increase by 37.5 mg per week up to 300 mg daily. (Maizels, 2005) (ICSI, 2007) *Trial period:* Some relief may occur in first two weeks; full benefit may not occur until six weeks. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation. ***Bupropion (Wellbutrin®)***, a second-generation non-tricyclic antidepressant (a noradrenaline and dopamine reuptake inhibitor) has been shown to be effective in relieving neuropathic pain of different etiologies in a small trial (41 patients). (Finnerup, 2005) While bupropion has shown some efficacy in neuropathic pain there is no evidence of efficacy in patients with non-neuropathic chronic low back pain. (Katz, 2005) Furthermore, a recent review suggested that bupropion is generally a third-line medication for diabetic neuropathy and may be considered when patients have not had a response to a tricyclic or SNRI. (Dworkin, 2007) *Side-effect profile:* Headache, agitation, insomnia, anorexia, weight loss *Dosing Information: Neuropathic pain (off-label indication):* 100 mg once daily, increase by 100 mg per week up to 200 mg twice daily. (Maizels, 2005) ***Selective serotonin reuptake inhibitors (SSRIs)***, a class of antidepressants that inhibit serotonin reuptake without action on noradrenaline, are controversial based on controlled trials. (Finnerup, 2005) (Saarto-*Cochrane*, 2005) It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain. (Namaka, 2004) More information is needed regarding the role of SSRIs and pain.

	Side Effects: Bleeding: An association has been found between the use of SSRI antidepressants and gastrointestinal bleeding. This risk is increased with the concomitant use of ASA or NSAIDs. It is suggested that the increased risk for GI bleeding be discussed with patients that have other risks for GI bleeding. An association with increased intraoperative blood loss has also been found with SSRI use. (Movig, 2003) A treatment option for those at risk for bleeding includes switching to an antidepressant with a lower degree of inhibition of serotonin reuptake (Intermediate reuptake: venlafaxine, amitriptyline, imipramine, citalopram; Low reuptake: desipramine, doxepin, trazodone, bupropion, mirtazapine). SSRIs with the highest degree of inhibition of serotonin reuptake include paroxetine, sertraline, and fluoxetine. (Looper, 2007)

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**